510(k) SUMMARY

K091065

J. MORITA USA Inc.'s

AIR TORX Type: TRA-200, TRA-200-CP3, TRA-200-CP4

1. NAME OF DEVICE

Trade or Proprietary Name: AIR TORX
Type: TRA-200, TRA-200-CP3, TRA-200-CP4

OCT 16 2009

Common Name: Handpiece, Air-powered, Dental

2. SUBMITTER NAME AND ADDRESS WITH PHONE/FAX

Registration No. 2081055	Registration No. 3002807636
Initial Distributor:	Manufacturer:
J. Morita USA, Inc.	J. MORITA MFG. CORP.
9 Mason	680 Higashihama Minami-cho
Irvine, CA 92618	Fushimi-ku, Kyoto
USA	Japan 612-8533
Telephone: 949-581-9600	+81-75-611-2141
Facsimile: 949-581-9688	+81-75-605-2354

3. CONTACT PERSON

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W.
Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331

4. DATE SUMMARY PREPARED: April 8, 2009

5. DEVICE CLASSIFICATION/CLASSIFICATION PANEL

The Air Torx has been classified as non-exempt Class I devices.

Device classification: 21CFR 872.4200
Dental handpiece and accessories

Device classification panel: 872 Dental Devices

6. DEVICE DESCRIPTION/SUBSTANTIAL EQUIVALENCE

DEVICE DESCRIPTION

This instrument is designed for dental treatment such as grinding, drilling and polishing teeth.

SUBSTANTIAL EQUIVALENCE

Comparison summary table with predicate device is as follows. AIR TORX and its predicate device has similar general intended uses, similar principles of operation, and similar technological characteristics. Although there are minor differences in the characteristics of the AIR TORX and its predicate devices, these differences do not raise new questions of safety or effectiveness.

Comparison summary table

Name and 510(k) number of predicate device: MICRO AIR MOTOR A-25LT, K944713

Technological characteristics	**Comparison result**
Indication for use	Similar
Target population	Similar
Design	Similar
Materials	Unknown
Performance	Similar
Sterility	Similar
Biocompatibility	Unknown
Mechanical safety	Similar
Chemical safety	Similar
Anatomical sites	Similar
Human factors	Similar
Energy used and/or delivered	Similar
Compatibility with environment and other devices	Similar
Where used	Similar
Standards met	Unknown
Electrical safety	N/A
Thermal safety	Unknown

7. INDICATIONS FOR USE

AIR TORX is used as a motor to drive attachments by air supplied from the treatment unit's air supply system.

Attachments are geared handpieces that are used to drill and polish teeth.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 18 2009

J. Morita USA, Incorporated
C/O Mr. Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, Northwest, Suite 1100
Washington, DC 20005

Re: K091065
Trade/Device Name: AIR TORX
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: September 30, 2009
Received: October 1, 2009

Dear Mr. Barritt:

This letter corrects our substantially equivalent letter of October 16, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): 091065

Device Name: AIR TORX

Indications For Use:

AIR TORX is used as a motor to drive attachments by air supplied from the treatment unit's air supply system.

Attachments are geared handpieces that are used to drill and polish teeth.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulloy for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091065